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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,812	10/11/2005	Bernhard Gleich	DE 030112	4273
	7590 08/03/200 LLECTUAL PROPER	EXAMINER		
P.O. BOX 3001 BRIARCLIFF MANOR, NY 10510			RAMIREZ, JOHN FERNANDO	
BRIARCLIFF	MANOK, NY 10510		ART UNIT	PAPER NUMBER
			3737	
			MAIL DATE	DELIVERY MODE
			08/03/2009	PAPER

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

		Applic	ation No.	Applicant(s)		
			2,812	GLEICH, BERNI	GLEICH, BERNHARD	
Office Action Summary		Exami	ner .	Art Unit		
		JOHN	F. RAMIREZ	3737		
T Period for R	he MAILING DATE of this commun eply	nication appears on	the cover sheet w	vith the correspondence a	nddress	
A SHOR' WHICHE - Extension after SIX ( - If NO peri - Failure to Any reply	TENED STATUTORY PERIOD F VER IS LONGER, FROM THE IN s of time may be available under the provision: 6) MONTHS from the mailing date of this com of for reply is specified above, the maximum s reply within the set or extended period for reply received by the Office later than three months tent term adjustment. See 37 CFR 1.704(b).	MAILING DATE OF s of 37 CFR 1.136(a). In no munication. tatutory period will apply an y will, by statute, cause the	THIS COMMUNI be event, however, may a d will expire SIX (6) MO application to become A	ICATION. reply be timely filed  NTHS from the mailing date of this BANDONED (35 U.S.C. § 133).		
Status						
2a)⊠ Th 3)⊡ Sir	sponsive to communication(s) files action is <b>FINAL</b> .  Ice this application is in condition sed in accordance with the pract	2b) ☐ This action is for allowance exce	ept for formal mat	· · · · · · · · · · · · · · · · · · ·	ne merits is	
Disposition	of Claims					
4a) 5)	tim(s) 39-63 is/are pending in the Of the above claim(s) is/a is/are allowed.  tim(s) 39-63 is/are rejected.  tim(s) is/are objected to.  tim(s) are subject to restri  Papers  specification is objected to by the	are withdrawn from				
App Re	drawing(s) filed on is/are blicant may not request that any objected to ath or declaration is objected to	ection to the drawing(s g the correction is req	s) be held in abeya uired if the drawing	nce. See 37 CFR 1.85(a). g(s) is objected to. See 37 (	, ,	
Priority und	er 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
2) Notice of 3) Information	References Cited (PTO-892) Draftsperson's Patent Drawing Review (I on Disclosure Statement(s) (PTO/SB/08) (s)/Mail Date	PTO-948)	Paper No	Summary (PTO-413) (s)/Mail Date Informal Patent Application 		

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#### **DETAILED ACTION**

### Response to Arguments

Applicant's arguments, see remarks, filed 04/21/09 with respect to new added claims 39-63 have been considered but are moot in view of the new ground(s) of rejection. The cancellation of claims 1-23 have been acknowledged.

## Specification

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

The abstract of the disclosure is objected to because the abstract does not set forth the nature and gist of the invention. Correction is required. See MPEP § 608.01(b).

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The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

### Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (I) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

#### Claim Objections

In claims 39 and 50, it is unclear how a magnetic field is generated with two different strengths, and therefore, it is also unclear how the spatial location of both subareas is changed. Thus, the scope of the claim is unclear.

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A prior art rejection has been applied to be pertinent, even though the examined claims do not clearly set forth the metes and bounds of the patent protection desired and are vague and indefinite. However, any subsequently presented claims, in definite form will be subject to the applied art rejection.

#### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 39-43, 49-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kraus, Jr et al. (6,470,220) in view of non-patent literature Daniel J. Hawrysz et al. "Developments toward Diagnostic Breast Cancer Imaging Using Near-Infrared Optical Measurements and Fluorescent Contrast Agent".

Kraus, Jr discloses an apparatus and method for heating magnetic particles in a target region by generating a magnetic field having a first low magnetic strength region and a second high magnetic strength region which is formed and changing the position in space of the sub-regions for so long and with such a frequency that the target region is heated, along with means for the acquisition and analysis of signals depending on the magnetization of the region of action [col. 13, lines 9-62; col. 14, lines 9-15 and see claim 1]. Kraus, Jr. further discloses that the signals induced in the region of action are

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received with the help of a coil arrangement [col. 13, lines 16-18; col. 9, lines 9-32] and delivering of an agent to a magnetic nano-or micro-particles to the tumor site [col. 3, lines 53-col. 4 line 5]. Kraus, Jr disclose the use of a contrast agent in which the total quantity of injected Tc99m is limited by the allowable radiation dose a subject may receive during the scintigraphy procedure. However, Kraus, Jr does not disclose the use of a detector which is modulated by interaction with rotating or oscillating the magnetic particles the target area to detect a signal as function of a change in rotation or oscillation of the magnetic particles due to modulation of the detected electromagnetic radiation.

Daniel J. Hawrysz et al. teach the use of near infrared fluorescent contrast agent in optical mammography, using *Frequency-domain photon migration* (FDPM) imaging techniques to measure optical properties by modulating incident light intensity sinusoidally (*see abstract, sections 2.2 and 2.3, figs. 2-3 and 15*). It would have been obvious for one of ordinary skill in the art at the time of the invention to modify the system and method disclosed by Kraus, Jr with the teachings of Daniel J. Hawrysz et al. to enhance the capabilities of the system and method, resulting in better tissue disease detection and diagnostic results.

Claims 6-10 and 57-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kraus, Jr in view of non-patent literature Daniel J. Hawrysz et al. or Hauger et al. (DE 199 30 408 A1) or Fercher et al. (DE 19624167 A1).

Kraus, Jr in view of Daniel J. Hawrysz et al. discloses all the subject matter as set forth above in claims 39 and 50, but it appears not to disclose an optical contrast

agent, in particular a fluorescent contrast agent, is introduced into or present in the examination area, detecting the scattered and/or reflected electromagnetic radiation and evaluating in a direction-dependent manner; detecting the change in intensity of the scattered and/or reflected electromagnetic radiation as a function of the oscillation mode or the rate of rotation; using electromagnetic radiation of at least one specific wavelength and/or wavelength spectrum, the radiation source is an optical fiber or a number of optical fibers, in particular integrated in a catheter or an endoscope.

However, in the same field of endeavor, Daniel J. Hawrysz et al. teach the use of near infrared fluorescent contrast agent in optical mammography, using Frequency-domain photon migration (FDPM) imaging techniques to measure optical properties by modulating incident light intensity sinusoidally (see abstract, sections 2.2 and 2.3, figs. 2 and 3). Furthermore, Hauger et al. teach the use of an OCT system comprising a scanner, an evaluation unit and display unit using an OCT beam in the infrared region to measure sectional images of biological samples (see Figures 1, 3, 4 and related description, see abstract, col. 4, line 5 – col. 5 line 65). Moreover, Fercher et al. teach the use of an OCT system to measure light beam of a coherence interferometer of biological samples (see Figure 6 and related description, see abstract).

It would have been obvious for one of ordinary skill in the art at the time of the invention to modify the system and method disclosed by Kraus, Jr with the teachings of Daniel J. Hawrysz et al. or Hauger et al. or Fercher et al. to enhance the capabilities of the system and method, resulting in a safer and more efficient medical procedure for tissue disease detection and diagnostic results.

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# **Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

Claims 39-61 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of US Patent No. 7,300,452.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter.

This is a <u>provisional</u> obviousness-type double patenting rejection.

Claims 39-61 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-8 and 11-17 of copending Application No. 10/270991.

This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

#### Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN F. RAMIREZ whose telephone number is (571)272-8685. The examiner can normally be reached on (Mon-Fri) 7:00 - 3:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN CASLER/ Supervisory Patent Examiner, Art Unit 3737

/J. F. R./ Examiner, Art Unit 3737